



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Biftu, et al.

Serial No.: 10/556,805

Docket No.: 21404P

Filed: November 14, 2005

For: 3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES  
AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE  
TREATMENT OR PREVENTION OF DIABETES

Art Unit: 1624

Examiner:

Brenda Coleman

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

APPLICATION FOR RECONSIDERATION OF PATENT TERM  
ADJUSTMENT UNDER 37 C.F.R. §1.705(b)

Sir:

This is a request for reconsideration of the patent term adjustment (PTA) indicated in the Notice of Allowance mailed January 15, 2009. This application is being submitted under 35 CFR §1.705 with the payment of the issue fee.

Applicants request that the PTA determination be corrected to include the days accrued pursuant to 37 CFR 1.702(b). The Patent Office delay under 1.702(b) is occurring more than three years after the subject application was filed and does not overlap with the 612 days due to delay under 37 CFR 1.702(a).

According to 37 CFR 1.702(a)(1), the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C. 371 in an international application. The requirements under section 371 for this international application were fulfilled on November 14, 2005. The date fourteen months after the section 371 requirements were fulfilled is January 14, 2007. A first office action was mailed on September

17, 2008, which constitutes 612 days of Patent Office delay under 37 CFR 1.703(a); i.e., the number of days from January 14, 2007 to September 17, 2008.

There were no circumstances constituting a failure of Applicants to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 CFR 1.704. Accordingly, the PTA accrued under 37 CFR 1.702(a)(1) is PTO Delay – Applicant Delay =  $612 - 0 = 612$  days.

According to 37 CFR 1.702(b), the term of the original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the national stage commenced under 35 U.S.C. 371. The date three years after commencement of the national stage is November 14, 2008. According to 37 CFR 1.703(b), the number of days accrued to date under Rule 1.702(b) is 151 days; i.e., the number of days from November 14, 2008 to April 14, 2009. The final determination cannot be made until an issue date for the patent is set.

There has been no delay due to Applicants during the 1.703(b) period. Accordingly, as of today Applicants are entitled to  $612 + 151 = 763$  days of PTA.

The PTA determination of the Patent Office (copy attached hereto as Exhibit 1) lists 612 days of Patent Office delay and 0 days of Applicant delay. The Patent Office PTA determination does not include the delay due to the failure to issue the patent within three years of the commencement of the national stage. The rationale for this omission is that the Patent Office has considered the delay under 37 CFR 1.702(a)(1) and 1.702(b) to be overlapping such that an applicant is entitled to the delay due to either 1.702(a)(1) or 1.702(b), whichever is longer, but not both. Reference is made, however, to Wyeth v. Dudas, Civil Action No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063 (DC, September 30, 2008) ("Wyeth"; copy attached hereto as Exhibit 2). The Wyeth case presents essentially the same factual situation as presented in the instant application. In Wyeth, the plaintiff argued that the time period due to actual Patent Office delay and the time period due to failure of the Office to issue the patent within 3 years of the filing date do not overlap unless there is actual overlap. The Court agreed, stating that, for purposes of determining PTA, the "only way that periods of time can 'overlap' is if they occur on the same day." Applying the Wyeth precedent to the instant situation, there is no actual overlap between the 612 days of Patent Office delay and the 151 days (and counting) due to failure to

issue a patent within three years. Accordingly, Applicants are entitled to the sum of the days arising from the two sources of delay.

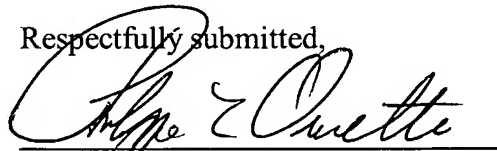
It is further noted that the patent that issues from the subject application will not be subject to a terminal disclaimer.

Accordingly, it is requested that the PTA determination for this application be changed to add the delay due to the Patent Office failure to issue a patent within 3 years to the earlier accrued 612 days of PTA.

The Commissioner is authorized to charge the fee set forth in § 1.18(e) to Deposit Account No. 13-2755.

Respectfully submitted,

By:



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Date: April 14, 2009

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Patricia Smiling Date 4-14-09

**EXHIBIT ONE**  
**USPTO Determination of Patent Term Adjustment**

10/556,805

**3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES AS DIPEPTIDYL PEPTIDASE  
INHIBITORS FOR THE TREATMENT OR PREVENTION OF DIABETES**01-21-  
2009::10:40:11**Patent Term Adjustments**

Patent Term Adjustment (PTA) for Application Number: 10/556,805

Filing or 371(c) Date:	11-14-2005	USPTO Delay (PTO) Delay (days):	612
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	0
Post-Issue Petitions (days):	+0	Total PTA (days):	612
USPTO Adjustment(days):	+0	Explanation Of Calculations	

**Patent Term Adjustment History**

Date	Contents Description	PTO(Days)	APPL(Days)
01-15-2009	Mail Notice of Allowance		
01-15-2009	Notice of Allowance Data Verification Completed		
01-15-2009	Case Docketed to Examiner in GAU		
01-15-2009	Document Verification		
01-05-2009	Examiner's Amendment Communication		
10-29-2008	Date Forwarded to Examiner		
10-02-2008	Response after Non-Final Action		
09-17-2008	Mail Non-Final Rejection	612	
09-15-2008	Non-Final Rejection	↑	
02-27-2006	Information Disclosure Statement considered	↑	
08-27-2007	Information Disclosure Statement considered	↑	
08-27-2007	Information Disclosure Statement considered	↑	
08-27-2007	Information Disclosure Statement (IDS) Filed	↑	
08-27-2007	Reference capture on IDS	↑	
08-27-2007	Information Disclosure Statement (IDS) Filed	↑	
08-27-2007	Information Disclosure Statement (IDS) Filed	↑	
08-27-2007	Information Disclosure Statement (IDS) Filed	↑	
08-09-2006	IFW TSS Processing by Tech Center Complete	↑	
02-27-2006	Information Disclosure Statement (IDS) Filed	↑	
02-27-2006	Information Disclosure Statement (IDS) Filed	↑	
11-14-2005	Preliminary Amendment	↑	
08-09-2006	Case Docketed to Examiner in GAU	↑	
11-14-2005	371 Completion Date	↑	
08-07-2006	Application Dispatched from OIPE	↑	
08-07-2006	Notice of DO/EO Acceptance Mailed	↑	
05-26-2006	Cleared by OIPE CSR	↑	
05-26-2006	Cleared by OIPE CSR	↑	
11-14-2005	Initial Exam Team nn	↑	

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EXHIBIT TWO

Wyeth v. Dudas, Civil Action No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063  
(DC, September 30, 2008)

1 of 1 DOCUMENT

WYETH, et al., Plaintiffs, v. JON W. DUDAS, Under Secretary of Commerce for  
Intellectual Property and Director of U.S. Patent and Trademark Office, Defendant.

Civil Action No. 07-1492 (JR)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2008 U.S. Dist. LEXIS 76063

September 30, 2008, Filed

COUNSEL: [\*1] WYETH, Plaintiff: David O. Bickart,  
LEAD ATTORNEY, Patricia A. Carson, PRO HAC  
VICE, KAYE SCHOLER LLP, Washington, DC.

For ELAN PHARMA INTERNATIONAL LIMITED,  
Plaintiff: David O. Bickart, LEAD ATTORNEY, KAYE  
SCHOLER LLP, Washington, DC.

For JON W. DUDAS, Honorable, Under Secretary of  
Commerce, Defendant: Fred Elmore Haynes, LEAD  
ATTORNEY, U.S. ATTORNEY'S OFFICE,  
Washington, DC.

JUDGES: JAMES ROBERTSON, United States District  
Judge.

OPINION BY: JAMES ROBERTSON

OPINION

**MEMORANDUM OPINION**

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever

the patent prosecution [\*2] takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

**Statutory Scheme**

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). [\*3] In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b)(1)(A), the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. See 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day [\*4] term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.<sup>1</sup> See 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period". ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

1 Certain reasons for exceeding the three-year pendency period are excluded, see 35 U.S.C. § 154(b)(1)(B)(i)-(iii), as are periods attributable to the applicant's own delay. See 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer [\*5] the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of "what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. §

154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, see 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under [\*6] 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is 1/1/07, but the patent does not [\*7] issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends



three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

### ***Chevron* Deference**

We must first decide whether the PTO's interpretation is entitled to deference under *Chevron v. NRDC*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in *Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006), and *United States v. Mead Corp.*, 533 U.S. 218, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001), Congress has not "delegated [\*8] authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority. See *Gonzales*, 546 U.S. at 255-56, citing *Mead*, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in *Merck*, the authority of the PTO is limited to prescribing "regulations establishing *procedures* for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the *circumstances that constitute a failure of an applicant* [\*9] to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term.

No such power is granted under § 154(b)(3)(A). *Chevron* deference does not apply to the interpretation at issue here.

### **Statutory Construction**

*Chevron* would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at *Chevron*'s "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., *MCI v. AT&T*, 512 U.S. 218, 229, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not [\*10] overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" *always overlaps* with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if [\*11] plaintiffs' construction is adopted, one cause of delay will be counted twice:

once because the PTO has failed to meet and administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefitted by it.

But if *subsection (B)* had been intended to guarantee a 17-year patent term and *no more*, it could easily have been written that way. It is true that the legislative context -- as distinct from the legislative history -- suggests that Congress may have intended to use *subsection (B)* to guarantee the 17-year term provided

before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in *subsection (A)*. The PTO's efforts to [\*12] prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON

United States District Judge